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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,700	04/21/2004	Chih-Chiang Yang	P464.312-0001	5387
164 7590 02/08/2008 KINNEY & LANGE, P.A. THE KINNEY & LANGE BUILDING 312 SOUTH THIRD STREET MINNEAPOLIS, MN 55415-1002			EXAMINER KRISHNAN, GANAPATHY	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 02/08/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/828,700	<b>Applicant(s)</b> YANG ET AL.	
	<b>Examiner</b> Ganapathy Krishnan	<b>Art Unit</b> 1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 8-14 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-14 and 16-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The amendment filed 12/18/2007 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

1. Claims 7 and 15 have been canceled.
2. Claims 6 and 14 have been amended.
3. Remarks drawn to rejections under 35 USC 112, second paragraph, 102 and 103.

Claims 1-6, 8-14 and 16-19 are pending in the case.

The finality of the previous office action (mailed 9/20/2007) has been withdrawn and the following new rejections are made of record.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 6 and 14 for recitation of the phrase "such as" has been overcome by amendment.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of Claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Bodor et al (Acta Pharm. Nord. 1989, 1(4), 185-193) and the rejection of Claim 19 under 35 U.S.C. 102(b) as being anticipated by Bodor et al (Acta Pharm. Nord. 1989, 1(4), 185-193), advanced in the previous office action have been overcome in view of applicants arguments. Applicants also pointed out that at page 13 of the specification, Example 5, line 1, the recitation, 'Span 60 or estriol' is a typographical error and should be 'Span 60 and estriol'. The example further recites the ratio of span 60 and estriol to be used in the preparation 9see interview summary of 12/31/2007).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of Claims 4-6 and 8 under 35 U.S.C. 103(a) as being unpatentable over Bodor et al (Acta Pharm. Nord. 1989, 1(4), 185-193) in view of Siguroardottir et al (Drug Development And Industrial Pharmacy, 1994, 20(9), 1699-1078) of record and Heiber et al (US 5,212,199) and the rejection of Claim 19 under 35 U.S.C. 102(b) as being anticipated by Bodor et al (Acta Pharm. Nord. 1989, 1(4), 185-193), advanced in the previous office action has been overcome in view of applicants arguments. The following new art rejections are made of record.

Claims 1-6, 8-14 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vyas et al (International Journal of Pharmaceutics, 1998, 172, 33-70) in view of Pitha (US 4,727,064) both newly cited.

Vyas et al, drawn to niosomes, teach the use of niosomes for drug delivery (abstract). Several types of non-ionic surfactant can be used for making the niosomes (page 35, right column, section 2 through page 41, left column). Vyas teaches the preparation of the niosome which comprises mixing an organic solution of surfactant/lipids and an aqueous solution of a drug to be encapsulated and the solvent removed to obtain the niosomes (page 44, left column). Niosomes using cholesterol and surfactants have been made (Page 54, left column). However, Vyas et al do not exemplify the preparation of niosomes wherein steroidal active agents complexed to cyclodextrins are used. But base on the teaching of Vyas one of skill in the art will recognize that other steroids similar to cholesterol can be used to make niosomes.

Pitha, drawn to cyclodextrin compositions, teaches formation of inclusion complexes between steroids like estradiol and hydroxypropyl-beta-cyclodextrin (col. 5, Tables 2 and 3; col. 7, example 4-5). Substantial amounts of the drug can be fitted into the cavity of the cyclodextrins (col. 5, lines 18-21) and the drugs solubility could be increased. Such complexes are also stable and lead to more efficient absorption of the drug (col. 1, lines 33-36).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising a niosome comprising the cyclodextrin derivatives and the surfactants as instantly claimed since the niosomes containing steroidal active agents analogous to the instant niosomes are seen to be taught in the prior art.

One of skill in the art would be motivated to make the compositions comprising the various active agents as instantly claimed using the process steps taught in the prior art and also use the niosomes in a method of transdermal delivery of steroidal active agents since niosomes containing drugs are able to penetrate the stratum corneum and appears promising for the transdermal delivery of even hydrophobic and amphiphilic drugs (Vyas, page 63, section 8.7- through page 64). Using complexes of cyclodextrin with the steroidal drugs would ensure more of the active agent being transported across the skin due to increased solubility.

It is well within the purview of one of ordinary skill in the art to adjust ratios of the active agents in order to optimize the composition and extend the scope.

***Response to Applicants Arguments Regarding Rejections Under 35 USC 103(a)***

In response to applicants arguments the art rejections advanced earlier have been withdrawn and the new art rejection above is made of record.

***Conclusion***

Claims 1-6, 8-14 and 16-19 are rejected

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK

  
Shaojia A. Jiang  
Supervisory Patent Examiner  
Art Unit 1623